IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

UNITED STATES OF AMERICA, ex rel. [UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Case No. 9:11-cv-01593-RMG **THIRD AMENDED COMPLAINT** **FILED UNDER SEAL** **PURSUANT TO 31 U.S.C. §3730(b)(2)**

DOCUMENT TO BE KEPT UNDER SEAL

William A. Coates
ROE CASSIDY COATES & PRICE, PA
1052 North Church Street
Greenville, South Carolina 29601
Tel: (864) 349-2600
Fax: (864) 349-0303

OF COUNSEL:
Peter W. Chatfield
PHILLIPS & COHEN LLP
2000 Massachusetts Ave. NW
Washington, D.C. 20036
Tel: (202) 833-4567
Fax: (202) 833-1815

Attorneys for [under seal]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

UNITED STATES OF AMERICA, ex rel. DR. MICHAEL MAYES, Plaintiffs, vs. BERKELEY HEARTLAB, INC., QUEST DIAGNOSTICS INCORPORATED, BLUEWAVE HEALTHCARE CONSULTANTS, INC., HEALTH DIAGNOSTIC LABORATORY, INC., and SINGULEX, INC., Defendants.	Case No. 9:11-cv-01593-RMG **THIRD AMENDED COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)** **JURY TRIAL DEMANDED**

Plaintiff-Relator Michael Mayes, through his attorneys Phillips & Cohen LLP and William A. Coates, on behalf of the United States of America (the "Government," or the "Federal Government"), for his Second Amended Complaint against defendants Berkeley HeartLab, Inc., Quest Diagnostics Incorporated, BlueWave Healthcare Consultants, Inc., Health Diagnostic Laboratory, Inc., and Singulex, Inc. (collectively, "Defendants"), alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made and caused to be made by Defendants and/or their agents, employees, and co-conspirators in violation of the federal False Claims Act, 31 U.S.C. §§ 3279 et seq. ("the FCA").

2. As detailed below, all named Defendants routinely pay kickbacks to physicians, physician practice groups, and hospitals to persuade such providers to order expensive blood[1] tests. At the time this lawsuit was filed, those kickbacks generally were masked as bogus and substantially inflated fees of two and a half or more times the standard Medicare reimbursement rate for drawing patient's blood. Such blood drawing payments are of a kind that the Department of Health and Human Services Office of Inspector General ("HHS-OIG") has specifically identified as implicating federal antikickback prohibitions. Through use of these kickbacks, Defendants cause providers to order tests that would not otherwise be ordered and may not be medically necessary or even useful.

3. In addition, the blood drawing fees paid to physicians create financial relationships between physicians and defendant laboratories, rendering any patient referrals to Defendants violations of the Stark Statute's prohibition against self-referral.

[1] Laboratories actually use different parts of the blood depending on the test conducted. Some tests use the plasma, others the serum and still others the "whole blood." However, these distinctions are irrelevant for the purposes of this complaint, thus all three will be categorized "blood."

4. Having been acquired by Defendant Quest Diagnostics Incorporated ("Quest") in or about May 2011, at its new parent corporation Quest's direction, defendant Berkeley HeartLab, Inc. ("Berkeley") stopped paying drawing fee kickbacks to at least some physicians and physician practice groups in January 2012. However, because Quest recognized that without the illegal payments many physicians would reduce the number of tests ordered from Berkeley or cease using Berkeley entirely, Berkeley and Quest began offering several new forms of remuneration in exchange for providers' continued business. These kickbacks, which Quest representatives acknowledge were developed in an effort to "get around" the drawing fee restrictions, include paying the salaries of providers' phlebotomists, leasing space from providers, providing valuable software services and paying exorbitantly high drawing fees for commercially insured patients.

5. Defendant Berkeley also performed tests, including tests for Plavix efficacy and vitamin D sufficiency and a test to determine whether a patient's heart was being continually overworked (the NT-proBNP test), which were not medically necessary and not ordered by the referring physicians. Similarly, defendants BlueWave Healthcare Consultants, Inc. ("BlueWave"), Health Diagnostic Laboratory, Inc. ("HDLab") and Singulex, Inc. ("Singulex") designed a panel of lab tests, combining tests from the two laboratories, and marketed by BlueWave as a panel that should be used as a baseline for every patient, even though the panel includes several Health Diagnostic Laboratory and Singulex tests that are only useful for very limited groups of patients. Defendants submitted or caused to be submitted claims for these medically unnecessary services to Medicare and other federal health care programs.

6. The FCA was enacted during the Civil War, and was substantially amended in 1986, and again in 2009 and 2010. Congress amended the Act in 1986 to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress

characterized as a primary tool for combating government fraud, was in need of modernization. The amendments create incentives for individuals to come forward with information about fraud against the government without fear of reprisals or Government inaction, and enable the use of private legal resources to prosecute fraud claims on the Government's behalf.

7. The FCA provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. §3729(a)(1)(G) (as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 [28 U.S.C. §2461 note; Public Law 104-410]).

8. The FCA allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendants during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

9. Federal laws, rules and regulations make it illegal to seek federal reimbursement for any procedure that was obtained by the payment of a kickback or through a non-exempt self-referral. Any claims submitted by Defendants or others for tests where Defendants paid the referring provider an excessive drawing fee or any other form of illegal remuneration are false and/or fraudulent claims within the meaning of the FCA.

10. Additionally, it is a violation of federal law to submit or cause the submission of claims to a federal health care program for services that were medically unnecessary. Any claims submitted by Defendants or others for tests that were not ordered by the treating physician or were otherwise not medically necessary are false and/or fraudulent claims within the meaning of the FCA.

11. Based on the foregoing laws, qui tam plaintiff Michael Mayes seeks, through this action, to recover damages and civil penalties arising from the false or fraudulent records, statements and/or claims that Defendants knowingly made or caused to be made in connection with its fraudulent scheme.

II. PARTIES

12. Plaintiff/Relator Michael Mayes ("Relator") is a resident of Hilton Head Island, South Carolina. Dr. Mayes attended Temple School of Medicine in Philadelphia, Pennsylvania and completed his residency in Internal Medicine at Temple Hospital in 1997 where he was recognized as the Most Outstanding Resident in his class. In 1999, Dr. Mayes joined Heritage Medical Partners in South Carolina. As of the date of filing, Dr. Mayes continues to practice with Heritage Medical Partners, a five physician practice specializing in internal medicine located on Hilton Head Island.

13. Defendant Berkeley HeartLab, Inc. is a corporation organized under the laws of the State of California, headquartered at 839 Mitten Road, Burlingame, California 94010. From October 2007 through May 2011, Berkeley was a wholly owned subsidiary of Celera Corporation. In May 2011, Celera Corporation was purchased by Quest Diagnostics Incorporated. Berkeley is in the business of providing cardiovascular disease management services, including laboratory services, to physicians, medical clinics and patients throughout the United States. Specifically, Berkeley provides low-density lipoprotein ("LDL") and cholesterol tests as well as several other tests used to identify those at risk for cardiovascular disease. In 2010, Berkeley received referrals from over 6,600 health care providers, processed over 220,000 samples, and performed approximately 1.9 million tests. Berkeley's top 150 referral sources represented 45% of its total sample volume. As of December 2010, Berkeley had 113 sales personnel across the country with the largest concentration in the Southeast and Texas.

14. Defendant Quest Diagnostics Incorporated is a corporation organized under the laws of the State of Delaware with its headquarters at 3 Giralda Farms, Madison, New Jersey 07940. Quest provides diagnostic testing services for cancer, cardiovascular disease, infectious disease and neurological disorders. Quest operates a nationwide specimen collection network including approximately 2,000 patient service centers and approximately 3,000 phlebotomists in physician offices. In 2011, Quest processed approximately 146 million test requisitions, generating net revenues of $7.5 billion. Since May of 2011, Quest has been the parent company for defendant Berkeley and, in that capacity, has assumed an active role in perpetuating and refining the unlawful inducements Berkeley had previously been using to gain lab test referrals. Relator sues Quest in this action because of Quest's role in perpetuating and refining unlawful inducements Berkeley had been using prior to its acquisition and has used after its acquisition by Quest.

15. Defendant BlueWave Healthcare Consultants, Inc. is a corporation headquartered at 307 Commercial Street SE, Hanceville, Alabama 35077-5518. BlueWave provides sales consulting services throughout the Southeast United States, and is currently expanding into other regions. BlueWave works closely with Defendants Health Diagnostic Laboratory, Inc. and Singulex, Inc.

16. Defendant Health Diagnostic Laboratory, Inc. is a Virginia corporation with its principal place of business at the Virginia Bio Technology Research Park in Richmond, Virginia 23219. HDLab is a laboratory testing company with about 425 employees. The company performs approximately 60,000 tests each day and expects to reach revenues of $250 million in 2012.

17. Defendant Singulex, Inc. is a Delaware Corporation with its principal place of business at 1650 Harbor Bay Parkway, Suite 200, Alameda, California 94502. Singulex provides laboratory testing services, including proprietary tests, and specializes in tests utilizing single-molecule counting technology.

III. JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Even if there had been any such public disclosure, Dr. Mayes is the original source of the allegations herein because prior to any relevant public disclosure, he has voluntarily disclosed to the Government the information in which the allegations or transactions in his claims are based, and/or because he has knowledge that is independent of and materially adds to any publically disclosed allegations or transactions relevant to his claims, and has voluntarily provided the information to the Government before filing this action.

19. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found to have transacted business in the District of South Carolina.

20. Venue is proper in the District of South Carolina pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact or have transacted business in this district. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this district, maintained employees and offices in this district, and/or made significant sales within this district.

IV. APPLICABLE LAW

A. The Anti-Kickback Statute

21. The federal health care Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), ("AKS") arose out of Congressional concern that financial inducements can influence health care decisions and result in goods and services being more expensive, medically unnecessary,

and harmful to patients. To protect the integrity of federal health care programs, Congress prohibited the payment of kickbacks in any form, regardless of whether the kickback actually gives rise to overutilization or unnecessary care. The AKS also reaches kickbacks concealed as legitimate transactions. See Social Security Amendments of 1972, Pub. L. No. 92-603, §§242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare and Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

22. The AKS prohibits any person or entity from making or accepting payments to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b). The statute prohibits laboratories from offering or paying any remuneration, in cash or kind, directly or indirectly, to induce or influence physicians or others to order or recommend laboratory services that may be paid for by federal health care programs. The AKS has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert denied, 474 U.S. 998 (1985).

23. Compliance with the AKS is a precondition to both participation as a health care provider in and payment under Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Program, and other federal health care programs.

24. For example, to establish eligibility and seek reimbursement from the Medicare Program, hospitals and other providers enter into Provider Agreements with CMS. As part of that agreement, the provider must sign the following certificate:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations and program instructions are available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and

> program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

25. Similarly, compliance with the federal Anti-Kickback and Stark Statutes is a prerequisite to a provider's right to receive or retain reimbursement payments from government-funded health care programs.

26. In sum, physicians, hospitals, and other providers who participate in federal health care programs must certify (often explicitly, in a provider agreement or on claim forms) that they have complied with the applicable federal rules and regulations, including the Anti-Kickback Statute.

27. Any party convicted under the Anti-Kickback Statute must be excluded from federal health care programs (i.e., not allowed to bill for services rendered) for a term of at least five years. 42 U.S.C. § 1320a-7(a)(1). Even without a conviction, if the Secretary of the Department of Health and Human Services ("HHS") finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency to exclude that provider from the State health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. § 1320a-7(b).

28. The enactment of these various provisions demonstrates Congress' commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback Statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicare and other federal health care programs.

29. Furthermore, the Affordable Care Act passed in 2010 explicitly confirms that any claim submitted to a federal health care program that includes items or services resulting from violations of the AKS constitutes a false or fraudulent claim for purposes of the False Claims Act. 42 U.S.C. § 1320a-7b(g).

30. HHS has promulgated certain safe harbor regulations that define practices that are not subject to the AKS including personal services or management contracts. 42 C.F.R. § 1001.952(d). However, this safe harbor protection is limited to contracts under which the aggregate compensation paid for the services is set in advance. Id. In addition, to be protected under the safe harbor, payment for the services must be consistent with fair market value. Id. at 1001.952(d)(5).

31. A 2005 OIG Advisory Opinion interpreted the AKS and the personal services or management contracts safe harbor as they would apply to a proposed "blood draw remuneration" program. Under the proposed program, a clinical laboratory would pay physicians $3 to $6 each time the physicians used their own phlebotomist to collect the blood sample of a patient referred to the laboratory for testing. See HHS-OIG Advisory Opinion No. 05-08, issued June 6, 2005. The Opinion concluded that the proposed arrangement "would clearly implicate the anti-kickback statute." Id.

32. The Advisory Opinion noted that the drawing fees would provide an "obvious financial benefit to the referring physician" and advised, "[w]here a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement,[2] an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory…." Id. The Opinion also states that, as a result of the physician's strong incentive to order more blood

[2] Medicare provides a $3 venipuncture fee when a physician draws blood to be used in laboratory testing, under CPT code 36415. However, this reimbursement is only allowed when: (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen; and (2) it is the customary practice of the physician performing such services to bill separate charges for them. See Medicare Claims Processing Manual, CMS Pub. 100-04, Chap. 16, section 60.1.1. Furthermore, only one collection fee is allowed for each patient encounter, regardless of the number of blood specimens drawn. See id. §60.1.

tests, "there is a risk of overutilization and inappropriate higher costs to the Federal health care programs." Id.

33. Furthermore, the Opinion evaluated whether the proposed program would fit under the personal services safe harbor provisions, but found that it would not, as the physicians would be paid on a per-patient basis and, thus, the aggregate compensation could never be set in advance. Id.

34. Safe harbor regulations also provide that certain space rental agreements (id. § 1001.952(b)) and provisions of items and services related to electronic health records (id. § 1001.952(y)) do not implicate the AKS. However, in order to receive the safe harbor protection, the rental charge or eligibility to receive the items or services must be determined without "tak[ing] into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs." Id. § 1001.952(b)(5); see also id. § 1001.952(b)(5).

B. The Stark Statute

35. A section of the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Statute") prohibits a hospital (or other entity providing healthcare items or services) from submitting Medicare claims for payment based on patient referrals from physicians having an improper "financial relationship" (as defined in the statute) with the provider. The regulations implementing 42 U.S.C. § 1395nn require that any entity collecting payments for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353.

36. The Stark Statute establishes that providers must not submit claims for items or services referred by physicians who have improper financial relationships with the providers of the items or services. In enacting the statute, Congress found that improper financial relationships between physicians and entities to which they refer patients can compromise the

physician's professional judgment as to whether an item or service is medically necessary, safe, effective, and of good quality. Congress relied on various academic studies consistently showing that physicians who had financial relationships with medical service providers used more of those providers' services than similarly situated physicians who did not have such relationships. The statute was designated specifically to reduce the loss suffered by the Medicare Program due to such increased questionable utilization of services.

37. Congress enacted the Stark Statute in two parts, commonly known as Stark I and Stark II. Stark I, enacted in 1989, applies to referrals of Medicare patients for clinical laboratory service made on or after January 1, 1992 by physicians with a prohibited financial relationship with the clinical lab provider. See Omnibus Budget Reconciliation Act of 1989, Pub. Law 101-239, § 6204. In 1993, Congress amended the Stark Statute (Stark II) to cover referrals for ten additional designated health services. See Omnibus Budget Reconciliation Act of 1993, Pub. Law 103-66, § 13562, Social Security Act Amendments of 1994, Pub. Law 103-432, §152.

38. In pertinent part, the Stark Statute provides:

> (a) Prohibition of certain referrals
>
> > (1) In general. Except as provided in subsection (b), if a physician (or an immediate family member of such physician has a financial relationship with an entity specified in paragraph (2), then--
> >
> > > (A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this title, and
> > >
> > > (B) the entity may not present or cause to be presented a claim under this title or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn(a)(1).

39. The Stark Statute broadly defines prohibited financial relationships to include any "compensation" paid directly or indirectly to a referring physician. The statute's

exceptions then identify specific transactions that will not trigger its referral and billing prohibitions.

40. Violations of Stark may subject the physician and the billing entity to exclusion from participation in federal health care programs and various financial penalties, including (a) a civil monetary penalty of $15,000 for each service included in a claim for which the entity knew or should have known the payment should not have been made under section 1395nn(g)(1) and (b) an assessment of three times the amount claimed for a service rendered pursuant to a referral the entity knows or should have known was prohibited. See 42 U.S.C. §§ 1395nn(g)(3), 1320a-71(a).

41. Certain service arrangements between physicians and billing entities may be protected under Stark's safe harbor provisions; however, they must meet certain requirements. The arrangement must be set out in writing, the services must be reasonable and necessary for the purposes of the arrangement, and the term of the arrangement must be at least one year. 42 U.S.C. § 1395nn(e)(3)(A)(i)-(iv). In addition, the compensation paid to the physician for the services provided must not exceed fair market value, and must not take into account the volume or value of any referrals or other business generated between the parties. Id. at § 1395nn(e)(3)(A)(v)

42. In sum, Stark prohibits laboratories from billing Medicare for designated services referred by a physician with whom the lab has a financial relationship of any type not falling within specific statutory exceptions. The statute specifically prohibits physicians, hospitals, and other providers from billing for such services. In-patient and out-patient hospital services are among the designated health services to which the Stark II referral and billing prohibitions apply.

C. Federal Health Care Programs

43. Medicare is a federally-funded health insurance program which provides for certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease.

44. The Medicare Program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

45. The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

46. Medicare coverage is limited to those items and services which are reasonable and medically necessary. 42 U.S.C. §1395y(a)(1). Health care practitioners and providers are required to ensure that all services are "provided economically and only when, and to the extent, medically necessary." 42 U.S.C. §1320c-5(a)(1),(3). Providers who furnish services or items substantially in excess of the needs of their patients may be excluded from participation in federal health care programs altogether. 42 U.S.C. §1320a-7(b)(6).

47. In order to enroll as a Medicare provider, clinical laboratories must complete Form CMS-855B. Form CMS-855B requires applicants to certify that they will "abide by the Medicare laws, regulations and program instructions," and to certify their understanding that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws regulations, and program instructions (including, but

not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with the applicable conditions of participation in Medicare.

48. By submitting CMS-855B, clinical laboratories certify that they are eligible for participation in the Medicare Program, and that they have complied with all applicable regulations and laws governing the program.

49. In addition to Medicare, the federal government pays for certain clinical laboratory services under several other federal health care programs, including but not limited to TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and federal workers' compensation programs.

50. TRICARE, administered by the United States Department of Defense, is a federally-funded program that provides medical benefits, including clinical services, to certain relatives of active duty, deceased, and retired service members or reservists, as well as to retirees. TRICARE sometimes provides for hospital services at non-military facilities for active duty service members as well. 10 U.S.C. §§ 1071-1110; 32 C.F.R. § 199.4(a).

51. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability.

52. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

V. BACKGROUND

A. Berkeley HeartLab

53. Berkeley HeartLab provides over 35 clinical diagnostic tests. The laboratory processes approximately 1,000 samples per day and performs over 200,000 tests per month.

54. Although Berkeley performs all testing out of their single laboratory located in Alameda, California, they have a nationwide network of sales representatives, and test patients across the country.

55. Berkeley offers a wide variety of tests that can be clinically useful for patients demonstrating risk factors for cardiovascular disease. However, even within the at-risk patient group, not every Berkeley tests is useful for every patient. For background purposes, the following are some of Berkeley's most frequently used tests:

a) LDL –S_3GGE – Measures the size of LDL particles, broken down into seven different subclasses. The size distribution can be clinically useful because smaller LDL particles, which can enter the artery wall more easily than large LDL particles may cause plaque buildup to progress much more quickly, increasing the risk of heart attack. Where LDL –S_3GGE results identify a patient as "at risk," follow-up testing may be warranted to monitor the patient's response to treatment. The CPT code for the LDL –S_3GGE lab, a Berkeley proprietary test, is 83701.

b) HDL –S_{10}GGE – Measures the size of high-density lipoprotein ("HDL") particles, broken down into five different subclasses. HDL helps prevent the buildup of plaque in the artery wall by removing LDL. The size distribution can be clinically useful because the larger HDL particles are more useful due to their increased ability to pick up LDL. Certain medications and lifestyle changes have been shown to increase levels of larger HDL particles, so follow-up testing may be warranted for at risk patients. The CPT code for the HDL –S_{10}GGE lab, a Berkeley proprietary test, is 82664.

c) Apolipoprotein B ("ApoB") – Directly measures the total amount of LDL. A high ApoB number indicates a high risk for heart disease. Follow-up ApoB

testing may be useful to monitor a patient's response to statin therapy. The CPT code for the ApoB test is 82172.

d) Lipoprotein (a) ("Lp(a)") – Measures the amount of the corkscrew-shaped Lp(a) protein which attaches to some LDL particles. This is not a genetic test, however, Lp(a) is inherited and can increase risk for heart attack and stroke. Diet and exercise have limited to no affect on lowering Lp(a), but certain medications may lower levels. Because high Lp(a) is genetically determined, follow-up testing would not be useful for patients whose Lp(a) tested in the normal range; however, follow-up testing may be clinically useful to monitor response to medication in a patient with high Lp(a). The CPT code for the Lp(a) test is 83695.

e) ApoE Genotype – Tests to determine a patient's apoE genotype, which helps identify how their body will respond to different amounts of dietary fat, specifically how likely the body is to incorporate fat into LDL formation. There are three types of apoE genotypes – apoE2, apoE3, and apoE4. People with an apoE4 have a greater risk for heart disease. Because it is a genetic test, no patient should need apoE testing more than once. The CPT codes for the ApoE Genotype test are 83891, 83892, 83896, 83898, 83903 and 83912.

f) KIF6 Genotype – Tests whether the patient is a carrier of the KIF6 gene variant. Those who are carriers are at greater risk for cardiac events and heart disease. Because it is a genetic test, no patient should need KIF6 Genotype testing more than once. The CPT codes for the KIF6 Genotype test are identical to those for the ApoE Genotype test, 83891, 83892, 83896, 83898, 83903 and 83912.

g) Lp-PLA_2 (the "Plac Test") – Tests for high levels of the blood enzyme Lp-PLA_2 which has been linked to inflammation in the artery wall and can help predict risk of heart attack or stroke. Follow-up testing may be useful to

monitor an at-risk patient's response to treatment, as both medications and lifestyle changes can reduce Lp-PLA_2 levels. The CPT code for the Lp-PLA_2 test is 83698.

h) C-Reactive Protein-hs (CRP) – Tests levels of CRP, a plasma protein produced by the liver in response to systemic inflammation. Thus, high levels of CRP indicate inflammation within the body, and can predict heart disease risk. Where CRP and Lp-LPA_2 levels are elevated, risk for heart attack or stroke are greatly increased. Medications and lifestyle changes have been shown to have anti-inflammatory benefits; therefore, follow-up testing may be warranted in certain at risk patients. The CPT code for the C-Reactive Protein-hs test is 86141.

i) NT-proBNP – Tests for the hormone NT-proBNP which is released from the cells of the heart muscle in response to ongoing stress or strain on the heart. NT-proBNP measurements are only relevant for patients with known or suspected cardiac disease. Follow-up testing may be useful in patients with high NT-proBNP levels after the treating physician has identified the cause of the strain on the heart and initiated a treatment plan. The CPT code for the NT-proBNP test is 83880.

j) CYP2C9 Genotype (the "Plavix Test") – Identifies a patient's CYP2C19 genotype, predicting the patient's ability to metabolize Plavix. Plavix (clopidogrel) is an agent that has been demonstrated to inhibit blood clots. However, certain patients, those without normal CYP2C19 metabolite function, are unable to effectively metabolize Plavix; in these patients, Plavix has actually been shown to increase rates of cardiovascular events. Thus, the Plavix test is used to determine whether Plavix should be used in a patient at risk for blood clots. Because it is a genetic test, a patient should not need the

Plavix test more than once. The CPT codes for the CYP2C9 Genotype test are 83891, 83900, 83901, 83914 and 83912.

k) Vitamin D - Test the patient's vitamin D sufficiency. The test is useful to identify patients who may be Vitamin D deficient, such as patients with osteoporosis or osteopenia. The CPT code for the Vitamin D test is 82306.

B. BlueWave, HDLab and Singulex

56. BlueWave promotes lab panels that combine tests offered by HDLab and Singulex. Many of the tests offered through the BlueWave-marketed panel are very similar to those offered by Berkeley, including the Lp(a) test, ApoE genotype test, Lp-PLA_2 test, CYP2C19 genotype test and Vitamin D test.

57. In addition, BlueWave's panels include several other HDLab and Singulex tests that are useful in certain, limited populations but that are not usually medically necessary and that thus do not warrant inclusion in routine test panels. These limited-use tests include:

a) Factor V Leiden – Tests for the presence of the Factor V Leiden genetic mutation. Factor V, which helps to activate an enzyme that causes blood to clot, is normally degraded by activated protein C, limiting the extent of clotting. In patients with Factor V Leiden, however, the factor V variant is not as easily degraded, thus leaving these patients at risk for excess clotting in the veins (known as venous thrombosis). Factor V Leiden testing is considered useful for patients with personal or family history of venous thrombosis. Experts agree that screening the general population for Factor V Leiden is not recommended.

b) Prothrombin Mutation – Tests for genetic mutation prothrombin G20210A. Prothrombin is a protein that is helps in the production of fibrin which causes the blood to clot. Individuals with the prothrombin G20210A mutation produce too much of the prothrombin protein, which makes the blood more

likely to clot when it should not. Prothrombin mutation testing is typically only used for patients who have experienced a blood clot in one of the deep veins of the body (known as deep vein thrombosis) or a blood clot that has traveled to the lung (called a pulmonary embolism).

c) Homocysteine – Measures levels of homocysteine, a chemical in the blood that, at elevated levels, may irritate the blood vessels causing hardening of the arteries or venous thrombosis. Testing homocysteine levels is typically appropriate in individuals with unexplained blood clots or unexplained atherosclerosis, and may also be used for patients suspected of Vitamin B-12 deficiency or folic acid deficiency. It is not, however, recommended as a test for the general population.

d) Methylenetetrahydrofolate reductase ("MTHFR") – Tests for genetic variant MTHFR, which can impair ability to process folic acid causing elevated homocysteine levels. MTHFR testing is not widely recommended for any patient population, but some consider it useful when testing has already shown homocysteine levels to be high or when a close relative has MTHFR gene mutations.

e) Myeloperoxidase ("MPO") – Test measuring the levels of MPO in the blood. MPO is an enzyme which, at elevated levels, is thought to render plaques unstable, thus increasing the risk that a patient with will have a cardiovascular event. MPO level testing may be useful for patients with a high risk of coronary artery disease, although routine testing is not recommended as the standard of care.

f) Galectin-3 – Measures levels of the protein galectin-3. In patients with chronic heart failure, elevated levels of galectin-3 have been associated with a higher risk of death. The utility of galectin-3 testing is limited to patients who have previously been diagnosed with chronic heart failure.

g) Apolipoprotein A1 – Tests the levels of Apolipoprotein A1, the major protein component of HDL in plasma, and helps to clear cholesterol from arteries. Low levels of Apolipoprotein A1 are, thus, associated with low levels of HDL and impaired clearance of excess cholesterol from the body.

h) Nonesterified Fatty Acids ("NEFA") – Measures the levels of nonesterified or "free" fatty acids, which are the major component of tryglycerides. Abnormally high levels of free fatty acids are associated with several diseases including diabetes mellitus and cardiovascular disease.

i) HS-Omega-3 Index – Evaluates an individual's omega-3 fatty acid levels as a percentage of total fatty acids. Higher omega-3 levels are associated with a number of health benefits including lower incidences of heart attacks and diabetes.

j) Cardiac Troponin-I ("cTnI") – Measures the concentration of Cardiac Troponin-I, which is released into the blood following heart damage. Physicians typically order cTnI tests only for patients with suspected active cardiac injury, such as acute myocardial infarction.

k) Interleukin-6 ("IL-6") – Quantifies the amount of Interleukin-6, a cytokine secreted by T cells and macrophages which stimulates immune response to trauma or infection. Elevated IL-6 may result from a wide variety of causes, including, among other things, coronary artery disease, diabetes, obesity and inadequate sleep. Because a finding of elevated IL-6 can be caused by many inflammatory processes, this very non-specific text is not needed as a routine test.

l) Interleukin-17A ("IL-17A") – Quantifies the amount of Interleukin-17, a cytokine that is produced by T-helper cells and assists in the body's immune response at the site of inflammation. The test's results are of limited use, as

IL-17A levels have been shown to be increased not only in patients with unstable angina and myocardial infarction, but also in smokers and patients with diabetes, autoimmune disease, periodontal disease, hyperlipidemia and hypertension. The test thus does not, by itself, provide significant insight into whether a serious health condition is likely to exist. As a result, there is no diagnostic justification of making such testing part of a routine test panel.

m) Parathyroid Hormone ("PTH") – Measures the concentration of parathyroid hormone, which increases the production of activated vitamin D, which then increases calcium absorption. PTH also decreases the body's reabsorption of phosphate. Thus, PTH is typically ordered only for patients with test results showing abnormal levels of vitamin D, calcium or phosphorus, or in some instances when a patient shows symptoms of abnormal calcium levels.

n) Ferritin – Measures the level of Ferritin, an iron-storing protein. Thus, Ferritin tests are typically considered useful only for patients with low levels of hemoglobin and hematocrit, suggesting iron deficiency anemia, or patients with symptoms suggesting iron overload.

VI. ALLEGATIONS

A. Defendants Paid Physicians Excessive "Drawing Fees" as an Inducement to Increase Referrals

58. Defendant Berkeley engaged in a nationwide scheme to pay certain physicians and physician groups a kickback disguised as a "drawing fee" for every patient referred to Berkeley's laboratories. After acquiring Celera Corporation, Quest continued to pay the drawing fee kickbacks for tests referred to Berkeley. Additionally, BlueWave, HDLab and Singulex contracted with laboratories to induce physician referrals through the payment of bogus and excessive drawing fees, which they termed "process and handling fees" that paid both for the blood draw and for other work related to preparing and sending off the the blood samples to HDLab and/or Singulex for testing. Whether Defendants styled these payments as

"drawing fees" and/or "process and handling fees," the payments ranged from more than three times to ten times the Medicare reimbursement rates for blood sample collection. Moreover, to the extent that such payments in excess of the $3 fee are sought to be justified as payment for services that extend beyond that inherently associated directly with drawing blood (such as purported "process and handling fees"), such remuneration was not being paid to reimburse for any provider services for which physician practices are not already compensated. This is so because compensation for all such services is already paid by federal health care programs as part of the categories of costs that are bundled into office visit reimbursement codes that reimburse physicians for their professional services and for related office expenses associated with providing services like processing and sending out lab test specimens. Moreover, each Defendants' purpose and intent in offering to pay such fees (or to assume the cost of paying phlebotomists stationed at physicians' offices in order to create added value to physicians' practices) was not simply to make physicians whole for purportedly "uncompensated" services but, at core, also to secure referrals from such physicians that Defendants understood would not be forthcoming in the absence of such inducements. As such, these payments constitute illegal kickbacks. See HHS-OIG Advisory Opinion No. 05-08, issued June 6, 2005.

1. Berkeley

59. Dr. Mayes began working as a member of the Heritage Medical Partners ("HMP") in January of 1999. On or about December of 2009, a Berkeley HeartLab representative met with the HMP physicians, presented Berkeley's panel of tests and services and offered the physicians an $11.50 "drawing fee" per referral. This is nearly four times the Medicare rate. These "drawing fees" are even higher with hospitals, which Berkeley pays up to $25 per patient referral.

60. At the end of each month, HMP submitted an invoice to Berkeley documenting every blood draw for every patient referred to Berkeley with the patient name, date, and

referring physician. Berkeley paid the "drawing fees" based on the information in this invoice.

61. Berkeley provided HMP with a standardized invoice form – with Berkeley's contact information pre-printed on it – to use to seek payment of the bogus "drawing fee."

62. Notwithstanding the drawing fees' highly inflated rates, when Berkeley first offered to pay HMP these bogus fees, Berkeley assured the physicians that the fees were permissible under the anti-kickback statute because they were purportedly "drawing fees."

63. Physicians, particularly those specializing in internal medicine, may order several tests a day for different patients, so the drawing fee reimbursements can grow to be quite substantial. Over the month of September 2010, Berkeley paid HMP physicians a total of $2,415.00 in draw fee remuneration for 210 patient referrals. Additionally, in the month of October 2010, HMP's five physician practice drew 235 blood samples for patients referred to Berkeley, and received $2,702.50 reimbursement. In total, in 2010, Berkeley paid HMP approximately $28,175 in blood draw remuneration for an estimated 2,450 patient referrals.

64. For example, in September of 2010, Berkeley paid HMP physicians $11.50 draw fee remuneration for each of the following Medicare-age-eligible patient referrals:

a) Patient T.R., age 65, who was treated by Dr. Lenns on September 1, 2010;

b) Patient G.T., age 80, who was treated by Dr. Long on September 1, 2010;

c) Patient H.M., age 73, who was treated by Dr. Long on September 1, 2010;

d) Patient H.C., age 82, who was treated by Dr. Long on September 2, 2010;

e) Patient L.R., age 75, who was treated by Dr. Lenns on September 2, 2010;

f) Patient C.W., age 68, who was treated by Dr. Lenns on September 7, 2010;

g) Patient C.C., age 73, who was treated by Dr. Long on September 7, 2010;

h) Patient T.C., age 73, who was treated by Dr. Scharold on September 7, 2010;

i) Patient B.D., age 78, who was treated by Dr. Long on September 8, 2010;

j) Patient J.G., age 86, who was treated by Dr. Long on September 8, 2010;

k) Patient J.E., age 89, who was treated by Dr. Lenns on September 8, 2010;

l) Patient E.F., age 70, who was treated by Dr. Lenns on September 8, 2010;

m) Patient M.L., age 74, who was treated by Dr. Scharold on September 8, 2010;

n) Patient D.H., age 72, who was treated by Dr. Petty on September 8, 2010;

o) Patient B.K., age 69, who was treated by Dr. Petty on September 8, 2010;

p) Patient H.B., age 74, who was treated by Dr. Petty on September 8, 2010;

q) Patient D.S., age 79, who was treated by Dr. Long on September 8, 2010;

r) Patient F.B., age 85, who was treated by Dr. Long on September 8, 2010;

s) Patient J.M., age 71, who was treated by Dr. Long on September 9, 2010;

t) Patient S.M., age 70, who was treated by Dr. Petty on September 9, 2010;

u) Patient L.A., age 74, who was treated by Dr. Lenns on September 9, 2010;

v) Patient G.L., age 70, who was treated by Dr. Lenns on September 10, 2010;

w) Patient P.L., age 69, who was treated by Dr. Lenns on September 10, 2010;

x) Patient F.K., age 78, who was treated by Dr. Lenns on September 10, 2010;

y) Patient E.B., age 73, who was treated by Dr. Long on September 10, 2010;

z) Patient J.W., age 66, who was treated by Dr. Lenns on September 10, 2010;

aa) Patient F.W., age 65, who was treated by Dr. Lenns on September 13, 2010;

bb) Patient J.C., age 83, who was treated by Dr. Long on September 13, 2010;

cc) Patient N.B., age 89, who was treated by Dr. Long on September 14, 2010;

dd) Patient J.G., age 76, who was treated by Dr. Lenns on September 14, 2010;

ee) Patient A.K., age 91, who was treated by Dr. Petty on September 14, 2010;

ff) Patient M.L., age 76, who was treated by Dr. Lenns on September 14, 2010;

gg) Patient R.E., age 65, who was treated by Dr. Lenns on September 14, 2010;

hh) Patient J.W., age 76, who was treated by Dr. Petty on September 14, 2010;

ii) Patient R.S., age 81, who was treated by Dr. Petty on September 14, 2010;

jj) Patient V.K., age 68, who was treated by Dr. Scharold on September 15, 2010;

kk) Patient M.D., age 70, who was treated by Dr. Long on September 15, 2010;

ll) Patient A.B., age 73, who was treated by Dr. Petty on September 15, 2010;

mm) Patient P.G., age 79, who was treated by Dr. Petty on September 15, 2010;

nn) Patient A.B., age 83, who was treated by Dr. Long on September 16, 2010;

oo) Patient N.A., age 72, who was treated by Dr. Lenns on September 16, 2010;

pp) Patient C.N., age 73, who was treated by Dr. Long on September 17, 2010;

qq) Patient G.L., age 79, who was treated by Dr. Lenns on September 17, 2010;

rr) Patient M.E., age 83, who was treated by Dr. Lenns on September 20, 2010;

ss) Patient A.M.B., age 83, who was treated by Dr. Lenns on September 20, 2010;

tt) Patient H.R., age 77, who was treated by Dr. Long on September 21, 2010;

uu) Patient S.P., age 67, who was treated by Dr. Petty on September 21, 2010;

vv) Patient R.D., age 67, who was treated by Dr. Scharold on September 22, 2010;

ww) Patient O.M., age 82, who was treated by Dr. Lenns on September 23, 2010;

xx) Patient A.L., age 67, who was treated by Dr. Petty on September 23, 2010;

yy) Patient R.C., age 74, who was treated by Dr. Long on September 23, 2010;

zz) Patient E.M., age 66, who was treated by Dr. Long on September 23, 2010;

aaa) Patient J.M., age 73, who was treated by Dr. Lenns on September 24, 2010;

bbb) Patient G.S., age 65, who was treated by Dr. Lenns on September 27, 2010;

ccc) Patient J.E., age 75, who was treated by Dr. Petty on September 27, 2010;

ddd) Patient I.L., age 87, who was treated by Dr. Petty on September 28, 2010;

eee) Patient E.L., age 87, who was treated by Dr. Long on September 28, 2010;

fff) Patient H.B., age 81, who was treated by Dr. Lenns on September 29, 2010;

ggg) Patient P.A., age 86, who was treated by Dr. Long on September 29, 2010;

hhh) Patient H.N., age 77, who was treated by Dr. Lenns on September 30, 2010;

iii) Patient T.D., age 85, who was treated by Dr. Long on September 30, 2010; and

jjj) Patient M.A., age 70, who was treated by Dr. Lenns on September 30, 2010.

65. Additionally, in October of 2010, Berkeley paid HMP physicians $11.50 draw fee remuneration for each of the following Medicare-age-eligible patient referrals:

a) Patient R.K., age 65, who was treated by Dr. Lenns on October 1, 2010;

b) Patient E.K., age 70, who was treated by Dr. Petty on October 1, 2010;

c) Patient L.D., age 80, who was treated by Dr. Petty on October 4, 2010;

d) Patient R.S., age 84, who was treated by Dr. Lenns on October 4, 2010;

e) Patient H.R., age 65, who was treated by Dr. Lenns on October 4, 2010;

f) Patient A.M., age 73, who was treated by Dr. Petty on October 4, 2010;

g) Patient H.S., age 78, who was treated by Dr. Scharold on October 4, 2010;

h) Patient K.L., age 74, who was treated by Dr. Scharold on October 4, 2010;

i) Patient B.G., age 81, who was treated by Dr. Long on October 5, 2010;

j) Patient C.M., age 75, who was treated by Dr. Petty on October 5, 2010;

k) Patient M.V., age 77, who was treated by Dr. Scharold on October 6, 2010;

l) Patient J.R., age 70, who was treated by Dr. Lenns on October 6, 2010;

m) Patient M.L., age 72, who was treated by Dr. Petty on October 7, 2010;

n) Patient N.F., age 77, who was treated by Dr. Petty on October 7, 2010;

o) Patient E.I., age 79, who was treated by Dr. Long on October 7, 2010;

p) Patient H.K., age 67, who was treated by Dr. Scharold on October 8, 2010;

q) Patient J.W., age 77, who was treated by Dr. Long on October 11, 2010;

r) Patient H.R., age 83, who was treated by Dr. Scharold on October 11, 2010;

s) Patient R.F., age 68, who was treated by Dr. Lenns on October 11, 2010;

t) Patient C.G., age 68, who was treated by Dr. Scharold on October 11, 2010;

u) Patient P.B., age 70, who was treated by Dr. Petty on October 11, 2010;

v) Patient A.D., age 65, who was treated by Dr. Long on October 12, 2010;

w) Patient D.H., age 76, who was treated by Dr. Petty on October 12, 2010;

x) Patient J.V., age 84, who was treated by Dr. Petty on October 12, 2010;

y) Patient J.F., age 75, who was treated by Dr. Petty on October 12, 2010;

z) Patient E.N., age 69, who was treated by Dr. Petty on October 12, 2010;

aa) Patient C.B., age 75, who was treated by Dr. Scharold on October 12, 2010;

bb) Patient F.T., age 76, who was treated by Dr. Long on October 13, 2010;

cc) Patient W.S., age 67, who was treated by Dr. Petty on October 13, 2010;

dd) Patient M.O., age 68, who was treated by Dr. Lenns on October 13, 2010;

ee) Patient W.S., age 82, who was treated by Dr. Petty on October 13, 2010;

ff) Patient S.B., age 73, who was treated by Dr. Petty on October 15, 2010;

gg) Patient J.M., age 82, who was treated by Dr. Lenns on October 18, 2010;

hh) Patient R.M., age 79, who was treated by Dr. Petty on October 18, 2010;

ii) Patient J.B., age 78, who was treated by Dr. Petty on October 18, 2010;

jj) Patient L.B., age 69, who was treated by Dr. Lenns on October 19, 2010;

kk) Patient P.R., age 66, who was treated by Dr. Petty on October 19, 2010;

ll) Patient C.M., age 67, who was treated by Dr. Long on October 20, 2010;

mm) Patient R.B., age 84, who was treated by Dr. Long on October 21, 2010;

nn) Patient C.L.S., age 75, who was treated by Dr. Long on October 21, 2010;

oo) Patient J.C., age 78, who was treated by Dr. Petty on October 21, 2010;

pp) Patient A.K., age 83, who was treated by Dr. Petty on October 21, 2010;

qq) Patient K.R., age 66, who was treated by Dr. Lenns on October 21, 2010;

rr) Patient E.E., age 73, who was treated by Dr. Petty on October 21, 2010;

ss) Patient A.P., age 75, who was treated by Dr. Scharold on October 21, 2010;

tt) Patient J.K., age 82, who was treated by Dr. Long on October 22, 2010;

uu) Patient R.M.M., age 72, who was treated by Dr. Petty on October 22, 2010;

vv) Patient D.I., age 81, who was treated by Dr. Lenns on October 22, 2010;

ww) Patient T.M., age 72, who was treated by Dr. Petty on October 22, 2010;

xx) Patient J.C., age 65, who was treated by Dr. Lenns on October 25, 2010;

yy) Patient A.W., age 72, who was treated by Dr. Lenns on October 25, 2010;

zz) Patient J.C., age 73, who was treated by Dr. Petty on October 25, 2010;

aaa) Patient L.R., age 67, who was treated by Dr. Long on October 26, 2010;

bbb) Patient S.M., age 73, who was treated by Dr. Long on October 26, 2010;

ccc) Patient E.M., age 83, who was treated by Dr. Petty on October 26, 2010;

ddd) Patient C.T., age 77, who was treated by Dr. Long on October 26, 2010;

eee) Patient A.S., age 81, who was treated by Dr. Petty on October 26, 2010;

fff) Patient K.L., age 78, who was treated by Dr. Long on October 27, 2010;

ggg) Patient T.P., age 85, who was treated by Dr. Long on October 27, 2010;

hhh) Patient S.W., age 72, who was treated by Dr. Petty on October 27, 2010;

iii) Patient M.H., age 70, who was treated by Dr. Long on October 28, 2010;

jjj) Patient R.G., age 80, who was treated by Dr. Long on October 28, 2010;

kkk) Patient E.L., age 71, who was treated by Dr. Lenns on October 28, 2010;

lll) Patient B.P, age 72, who was treated by Dr. Long on October 29, 2010;

mmm) Patient F.R., age 76, who was treated by Dr. Lenns on October 29, 2010;

nnn) Patient G.H., age 77, who was treated by Dr. Long on October 29, 2010;

66. Dr. Mayes can provide information about additional patients upon request.

67. Because their tests focus on risk factors for cardiovascular disease, a high percentage of the patients tested by Berkeley are elderly, and covered by Medicare. In 2010, revenues from Medicare patients represented approximately 53% of the total Berkeley patient test service revenues.

68. For example, Berkeley paid HMP $11.50 for each referral of the following Medicare patients:

a) Patient G.F., whom HMP referred to Berkeley in March 2010, August 2010 and January 2011, receiving a total of $34.50 in referral fees. Berkeley billed Medicare for the tests performed as a result of patient G.F.'s referrals and Medicare reimbursed Berkeley $1,041.42.

b) Patient M.A.F., whom HMP referred to Berkeley in January 2011. Berkeley submitted claims to Medicare for the tests and was reimbursed $599.96.

c) Patient M.T.F., whom HMP referred to Berkeley in April 2011. Berkeley billed Medicare for patient M.T.F.'s tests and was reimbursed $1,063.40.

69. Additionally, in January 2011 alone, Berkeley paid HMP physicians $11.50 for each of the following Medicare patient referrals:

a) Patient M.M., age 78, who was treated by Dr. Petty on January 3, 2011;

b) Patient D.W., age 76, who was treated by Dr. Lenns on January 3, 2011;

c) Patient L.S., age 71, who was treated by Dr. Long on January 3, 2011;

d) Patient D.H., age 82, who was treated by Dr. Long on January 3, 2011;

e) Patient N.L., age 73, who was treated by Dr. Petty on January 3, 2011;

f) Patient D.H., age 73, who was treated by Dr. Petty on January 3, 2011;

g) Patient M.M., age 66, who was treated by Dr. Lenns on January 4, 2011;

h) Patient J.W., age 70, who was treated by Dr. Petty on January 4, 2011;

i) Patient J.K., age 84, who was treated by Dr. Long on January 4, 2011;

j) Patient J.V., age 78, who was treated by Dr. Lenns on January 4, 2011;

k) Patient J.P., age 84, who was treated by Dr. Lenns on January 4, 2011;

l) Patient P.B., age 65, who was treated by Dr. Petty on January 4, 2011;

m) Patient K.V., age 67, who was treated by Dr. Lenns on January 4, 2011;

n) Patient T.S., age 68, who was treated by Dr. Lenns on January 4, 2011;

o) Patient B.H., age 65, who was treated by Dr. Petty on January 4, 2011;

p) Patient J.G., age 79, who was treated by Dr. Petty on January 4, 2011;

q) Patient L.M., age 78, who was treated by Dr. Petty on January 4, 2011;

r) Patient R.N., age 71, who was treated by Dr. Binamira on January 5, 2011;

s) Patient R.S., age 88, who was treated by Dr. Petty on January 5, 2011;

t) Patient N.M., age 71, who was treated by Dr. Long on January 5, 2011;

u) Patient T.M., age 71, who was treated by Dr. Long on January 5, 2011;

v) Patient M.S., age 65, who was treated by Dr. Lenns on January 5, 2011;

w) Patient M.M., age 74, who was treated by Dr. Petty on January 5, 2011;

x) Patient B.M., age 75, who was treated by Dr. Long on January 5, 2011;

y) Patient A.S., age 77, who was treated by Dr. Petty on January 5, 2011;

z) Patient J.G., age 70, who was treated by Dr. Lenns on January 5, 2011;

aa) Patient F.W., age 75, who was treated by Dr. Long on January 5, 2011;

bb) Patient L.L., age 65, who was treated by Dr. Petty on January 5, 2011;

cc) Patient F.A., age 77, who was treated by Dr. Lenns on January 6, 2011;

dd) Patient P.M.W., age 67, who was treated by Dr. Petty on January 6, 2011;

ee) Patient G.T., age 80, who was treated by Dr. Long on January 6, 2011;

ff) Patient L.C., age 76, who was treated by Dr. Lenns on January 6, 2011;

gg) Patient M.E., age 82, who was treated by Dr. Petty on January 6, 2011;

hh) Patient G.S., age 66, who was treated by Dr. Lenns on January 6, 2011;

ii) Patient S.B., age 74, who was treated by Dr. Petty on January 6, 2011;

jj) Patietn D.W., age 74, who was treated by Dr. Lenns on January 6, 2011;

kk) Patient R.W., age 69, who was treated by Dr. Lenns on January 6, 2011;

ll) Patient T.M., age 78, who was treated by Dr. Lenns on January 6, 2011;

mm) Patient K.D., age 83, who was treated by Dr. Lenns on January 6, 2011;

nn) Patient F.A., age 78, who was treated by Dr. Petty on January 7, 2011;

oo) Patient W.P.., age 81, who was treated by Dr. Lenns on January 7, 2011;

pp) Patient A.A., age 82, who was treated by Dr. Petty on January 7, 2011;

qq) Patient J.G., age 66, who was treated by Dr. Lenns on January 7, 2011;

rr) Patient J.T.L., age 68, who was treated by Dr. Lenns on January 7, 2011;

ss) Patient H.R., age 93, who was treated by Dr. Long on January 7, 2011;

tt) Patient I.G., age 70, who was treated by Dr. Lenns on January 10, 2011;

uu) Patient G.R., age 74, who was treated by Dr. Long on January 10, 2011;

vv) Patient J.P., age 87, who was treated by Dr. Petty on January 10, 2011;

ww) Patient D.P., age 77, who was treated by Dr. Lenns on January 10, 2011;

xx) Patient D.D.B., age 68, who was treated by Dr. Lenns on January 10, 2011;

yy) Patient V.V.A., age 75, who was treated by Dr. Petty on January 10, 2011;

zz) Patient D.B., age 65, who was treated by Dr. Petty on January 10, 2011;

aaa) Patient J.M., age 67, who was treated by Dr. Petty on January 10, 2011;

bbb) Patient L.A., age 74, who was treated by Dr. Lenns on January 10, 2011;

ccc) Patient K.S., age 68, who was treated by Dr. Petty on January 11, 2011;

ddd) Patient W.H., age 75, who was treated by Dr. Binamira on January 11, 2011;

eee) Patient M.J.F., age 67, who was treated by Dr. Long on January 12, 2011;

fff) Patient D.P., age 71, who was treated by Dr. Petty on January 12, 2011;

ggg) Patient J.F., age 65, who was treated by Dr. Petty on January 12, 2011;

hhh) Patient L.D., age 80, who was treated by Dr. Petty on January 12, 2011;

iii) Patient J.H., age 77, who was treated by Dr. Lenns on January 12, 2011;

jjj) Patient H.C., age 82, who was treated by Dr. Long on January 13, 2011;

kkk) Patient D.E., age 83, who was treated by Dr. Petty on January 13, 2011;

lll) Patient J.G., age 86, who was treated by Dr. Long on January 13, 2011;

mmm) Patient J.D., age 82, who was treated by Dr. Lenns on January 13, 2011;

nnn) Patient J.D., age 74, who was treated by Dr. Petty on January 13, 2011;

ooo) Patient V.D., age 67, who was treated by Dr. Petty on January 13, 2011;

ppp) Patient K.B., age 73, who was treated by Dr. Lenns on January 13, 2011;

qqq) Patient D.B., age 74, who was treated by Dr. Petty on January 13, 2011;

rrr) Patient L.C., age 78, who was treated by Dr. Long on January 14, 2011;

sss) Patient P.D., age 69, who was treated by Dr. Lenns on January 14, 2011;

ttt) Patient J.A., age 66, who was treated by Dr. Petty on January 14, 2011;

uuu) Patient M.M., age 79, who was treated by Dr. Lenns on January 14, 2011;

vvv) Patient P.A., age 73, who was treated by Dr. Petty on January 14, 2011;

www) Patient J.M., age 71, who was treated by Dr. Long on January 14, 2011;

xxx) Patient P.M., age 76, who was treated by Dr. Binamira on January 14, 2011;

yyy) Patient B.B., age 81, who was treated by Dr. Long on January 17, 2011;

zzz) Patient G.M., age 77, who was treated by Dr. Long on January 17, 2011;

aaaa) Patient C.B., age 79, who was treated by Dr. Long on January 17, 2011;

bbbb) Patient M.B., age 79, who was treated by Dr. Long on January 17, 2011;

cccc) Patient M.S., age 66, who was treated by Dr. Petty on January 17, 2011;

dddd) Patient E.C., age 81, who was treated by Dr. Long on January 18, 2011;

eeee) Patient A.H., age 83, who was treated by Dr. Long on January 18, 2011;

ffff) Patient J.H., age 68, who was treated by Dr. Long on January 18, 2011;

gggg) Patient M.H., age 84, who was treated by Dr. Lenns on January 18, 2011;

hhhh) Patient N.L., age 78, who was treated by Dr. Long on January 18, 2011;

iiii) Patient A.M., age 73, who was treated by Dr. Petty on January 18, 2011;

jjjj) Patient M.L.W., age 76, who was treated by Dr. Lenns on January 18, 2011;

kkkk) Patient R.C., age 77, who was treated by Dr. Petty on January 18, 2011;

llll) Patient V.M., age 65, who was treated by Dr. Petty on January 18, 2011;

mmmm) Patient W.R., age 73, who was treated by Dr. Petty on January 18, 2011;

nnnn) Patient L.C., age 70, who was treated by Dr. Petty on January 18, 2011;

oooo) Patient L.B., age 90, who was treated by Dr. Petty on January 19, 2011;

pppp) Patient P.M., age 74, who was treated by Dr. Long on January 19, 2011;

qqqq) Patient C.R., age 68, who was treated by Dr. Petty on January 19, 2011;

rrrr) Patient L.S., age 70, who was treated by Dr. Long on January 20, 2011;

ssss) Patient G.S., age 66, who was treated by Dr. Lenns on January 20, 2011;

tttt) Patient R.M., age 82, who was treated by Dr. Lenns on January 20, 2011;

uuuu) Patient G.H., age 73, who was treated by Dr. Long on January 21, 2011;

vvvv) Patient P.S., age 78, who was treated by Dr. Lenns on January 21, 2011;

wwww) Patient E.H., age 75, who was treated by Dr. Lenns on January 21, 2011;

xxxx) Patient D.W., age 65, who was treated by Dr. Long on January 21, 2011;

yyyy) Patient B.B., age 81, who was treated by Dr. Petty on January 21, 2011;

zzzz) Patient A.B., age 91, who was treated by Dr. Long on January 21, 2011;

aaaaa) Patient J.D., age 66, who was treated by Dr. Petty on January 21, 2011;

bbbbb) Patient D.R., age 91, who was treated by Dr. Petty on January 21, 2011;

ccccc) Patient M.H., age 72, who was treated by Dr. Lenns on January 24, 2011;

ddddd) Patient M.M., age 73, who was treated by Dr. Long on January 24, 2011;

eeeee) Patient M.R., age 71, who was treated by Dr. Petty on January 24, 2011;

fffff) Patient R.W., age 77, who was treated by Dr. Petty on January 24, 2011;

ggggg) Patient R.Y., age 68, who was treated by Dr. Petty on January 24, 2011;

hhhhh) Patient F.M., age 65, who was treated by Dr. Lenns on January 24, 2011;

iiiii) Patient J.F., age 87, who was treated by Dr. Long on January 25, 2011;

jjjjj) Patient B.D., age 66, who was treated by Dr. Petty on January 25, 2011;

kkkkk) Patient L.S., age 68, who was treated by Dr. Long on January 25, 2011;

lllll) Patient E.R., age 71, who was treated by Dr. Long on January 25, 2011;

mmmmm) Patient B.W., age 73, who was treated by Dr. Long on January 26, 2011;

nnnnn) Patient D.K., age 66, who was treated by Dr. Long on January 26, 2011;

ooooo) Patient N.E., age 69, who was treated by Dr. Long on January 26, 2011;

ppppp) Patient V.M., age 89, who was treated by Dr. Long on January 26, 2011;

qqqqq) Patient J.C., age 66, who was treated by Dr. Binamira on January 26, 2011;

rrrrr) Patient L.L., age 83, who was treated by Dr. Petty on January 26, 2011;

sssss) Patient R.B., age 79, who was treated by Dr. Petty on January 26, 2011;

ttttt) Patient C.H., age 81, who was treated by Dr. Petty on January 26, 2011;

uuuuu) Patient C.C., age 79, who was treated by Dr. Petty on January 27, 2011;

vvvvv) Patient A.T., age 80, who was treated by Dr. Lenns on January 27, 2011;

wwwww) Patient K.K., age 89, who was treated by Dr. Long on January 27, 2011;

xxxxx) Patient R.W., age 66, who was treated by Dr. Petty on January 27, 2011;

yyyyy) Patient B.D., age 70, who was treated by Dr. Long on January 27, 2011;

zzzzz) Patient E.W., age 91, who was treated by Dr. Petty on January 28, 2011;

aaaaaa) Patient J.K., age 78, who was treated by Dr. Long on January 31, 2011;

bbbbbb) Patient J.L., age 81, who was treated by Dr. Rizk on January 31, 2011;

cccccc) Patient M.B., age 76, who was treated by Dr. Rizk on January 31, 2011;

dddddd) Patient R.G., age 80, who was treated by Dr. Petty on January 31, 2011; and

eeeeee) Patient M.H., age 83, who was treated by Dr. Petty on January 31, 2011.

70. Berkeley also paid HMP blood draw remuneration for referrals of the following Medicare Advantage patients:

a) Patient L.S., who was referred to Berkeley by HMP and tested in January 2011. Berkeley billed Aetna's Medicare Advantage plan for the tests and was reimbursed $483.32.

b) Patient J.B., who was referred to Berkeley by HMP and tested in March 2011. Berkeley billed United Healthcare's Medicare Advantage plan for the tests and was reimbursed $1,386.00.

c) Patient W.B., who was referred to Berkeley by HMP and tested in March 2011. Berkeley billed United Healthcare's Medicare Advantage plan for the tests and was reimbursed $1,386.00.

71. Relator knows of other physician practices that received drawing fee kickback payments for referring patients to Berkeley. Relator has also had conversations with Berkeley's sales representative indicating that the practice of paying these drawing fees is not limited to HMP and extends to hospitals. Berkeley offered these "drawing fees" to physicians and hospitals nationwide.

2. Quest Diagnostics

72. Following Quest's acquisition of Berkeley's parent company, Celera Corporation, in May 2011, Berkeley and Quest continued to pay physicians the excessive drawing fees Berkeley had promised through the end of January 2012.

73. Immediately following the acquisition, the drawing fee invoices continued to bear the Berkeley logo and the drawing fee payments were made via Berkeley checks. On December 27, 2011, Berkeley issued a letter to HMP informing the physicians that they would be terminating the draw fee payment program as of January 31, 2012. On January 10, 2012, Quest representative Marc Biemiller met with the HMP physicians to discuss the program's end. Although Biemiller acknowledged that the termination of the drawing fees stemmed from Quest's concerns about the legality of the program, Quest did not cease the payments immediately. Instead, it continued to pay physicians for referrals through the end of January 2012. Payment records confirm that Quest knew of, and ultimately directly participated in the kickback payments: the final two payments, dated February 15, 2012 and March 19, 2012, were identified as "BHL – BLOOD DRAWS," but issued by Quest. Moreover, as is explained

in greater detail below, shortly after the announcement in December, 2011, that Quest planned to terminate Berkeley's excessive draw fee payments, Quest suggested several methods through which it could pay the physicians kickbacks in less obvious forms in order to make up for the loss of the drawing fee income.

74. On facts alleged and on information and belief, Quest and Berkeley worked together to pay physicians inflated drawing fees, which they knew to be illegal forms of remuneration.

75. Additionally, when explaining how Berkley draw fee payments to physicians were being eliminated under Quest's ownership of the company, Biemiller noted the existence of $25 draws that Berkley had been paying hospitals and the fact that such payments would be continuing.

3. BlueWave, HDLab and Singulex

76. In or about June of 2011, Relator spoke with a physician's assistant ("PA") who had worked for a physician in Beaufort. She informed Relator that at the beginning of her employment, the physician usually referred patients to Berkeley for testing and received a $10 blood draw fee for each patient referral. However, in or around 2011, the physician was approached by representatives from BlueWave who offered him $20 blood draw remuneration per patient referral if the physician would sign a one year contract with an agreement to order all non-basic lab tests through BlueWave. The physician agreed, ceased ordering tests from Berkeley and began ordering all lab tests through BlueWave.

77. In or about July, 2012, an Abbott Laboratories ("Abbott") sales representative, Matthew Peters, visited Heritage Medical Partners' offices with Abbott physician consultant, Dr. Barry Hull, based in Peachtree City, Georgia, to promote Abbott pharmaceutical products, Tricor, Trilipix and Niaspan. While there, Dr. Hull spoke with Relator's partner, Dr. Long, and recommended ordering laboratory tests through BlueWave because of the company's high draw fee payments. Dr. Hull promoted BlueWave's drawing fees as a good source of

"supplemental income" and bragged that his office brings in around $17,000 per month in drawing fee remuneration, approximately $200,000 annually. Dr. Hull also reported that BlueWave, HDLab and Singulex do not "balance bill" patients, meaning that they accept as payment whatever a patient's insurer will reimburse, essentially waiving the patient's co-pay.

78. Following this conversation with Dr. Hull, Dr. Long invited BlueWave to HMP's offices. On July 27, 2012, two BlueWave representatives, Tony Carnaggio and Cal Dent, met with the HMP physicians to promote their products. BlueWave claimed that their partner laboratories, HDLab and Singulex, provide a test profile very similar to Berkeley and offered the physicians a total of $30 "process and handling" fee remuneration for each patient lab referral, $20 from HDLab[3] and $10 from Singulex.

79. Although redesignated as payments for "process and handling," this remuneration does not cover any provider services that are not services already compensated for as part of the phlebotomist's blood draw fee (such as "apportioning the specimen into multiple vials specific to whole blood, serum, plasma and urine testing requirements" and "labeling the vials specific to the category of testing to be performed") and/ or that are bundled into office visit reimbursement codes that already reimburse physicians for their professional and related office expenses related associated services like processing lab test specimens that regularly make up part of patients' office visits (such as "obtaining patient demographic and insurance information," "labeling shipping forms with proper disclosure," and centrifuging and/or refrigerating blood specimens to be sent to labs). Such arrangements thus are not legitimate compensation paid to compensate physicians for work they would otherwise not be paid for doing. Rather, the payments have been made for the intended purpose of securing lab test referrals that would not otherwise be forthcoming from such physicians and that often are not medically necessary or, often, even marginally helpful. Such

[3] HDL's written agreement breaks this down into $17 for "process and handling" services and $3 for phlebotomist services.

payments thus are in all cases unlawful kickbacks being offered and paid by BlueWave in conjunction with its co-conspirators, test providers HDLab and Singulex.

80. Relator spoke separately with Blue Wave's Tony Carnaggio in a phone call on August 13, 2012. During that call Carnaggio confirmed that the physicians would be paid $30 total for each HDLab and Singulex lab panel ordered through BlueWave, and informed Relator that the physicians could order, and Medicare would reimburse for, follow up lab panels ordered once every three months. Carnaggio also confirmed that patients would not be required to pay any part of the cost of the labs ordered from HDLab and Singulex via BlueWave, as they accept whatever amount is paid by patients' insurance.

81. In addition to Dr. Barry Hull, Relator knows of other physicians who receive high "process and handling" referral payments from BlueWave, HDLab and Singulex, including Dr. Gaston "Gus" Perez of Bluffton, SC, Dr. Timothy Scharold of Bluffton, SC, Dr. Daniel Ripley of Beaufort, SC, and Dr. Luann Aquino of Hilton Head Island, SC. According to Tony Carnaggio, the largest primary care group in Savannah, GA, and the largest cardiology group in Columbia, SC, also order HDLab and Singulex lab profiles through BlueWave and, upon information and belief, are paid per referral. Upon information and belief, a high percentage of the labs performed as a result of the BlueWave, HDLab and Singulex patient referral payments will be reimbursed by Medicare and other federal health care programs.

82. Soon after the July 27, 2012 meeting between HMP and Bluewave, and over Dr. Mayes' objections, the other physicians at HMP accepted Bluewave, HDL, and Singulex's offer and began submitting lab tests in exchange for payment of the inflated draw and processing and handling fees alleged above.

83. Based on the arrangements that Bluewave made on behalf of itself, HDL, and Singulex, HDL thereafter paid HMP physicians $20 draw and P&H fees, and Singulex paid

$10 draw and P&H fees for (among others) each of the following Medicare eligible patients during the period between August 2012 and April 2013:

a) Patient J.K., age 72, who was treated by Dr. Lenns on August 30, 2012;

b) Patient R.M., age 69, who was treated by Dr. Long on September 4, 2012;

c) Patient R.A., age 70, who was treated by Dr. Lenns on September 6, 2012;

d) Patient H.F., age 73, who was treated by Dr. Lenns on September 7, 2012;

e) Patient G.O., age 67, who was treated by Dr. Petty on September 10, 2012;

f) Patient R.B., age 76, who was treated by Dr. Long on September 11, 2012;

g) Patient R.B., age 75, who was treated by Dr. Long on September 11, 2012;

h) Patient J.C., age 67, who was treated by Dr. Binamira on September 11, 2012;

i) Patient C.C., age 81, who was treated by Dr. Petty on September 13, 2012;

j) Patient J.F., age 88, who was treated by Dr. Long on September 13, 2012;

k) Patient H.N., age 70, who was treated by Dr. Long on September 13, 2012;

l) Patient M.B., age 94, who was treated by Dr. Binamira on September 14, 2012;

m) Patient R.K., age 86, who was treated by Dr. Petty on September 14, 2012;

n) Patient A.H., age 69, who was treated by Dr. Petty on September 14, 2012;

o) Patient G.M., age 87, who was treated by Dr. Long on September 14, 2012;

p) Patient M.N., age 75, who was treated by Dr. Long on September 14, 2012;

q) Patient L.B., age 76, who was treated by Dr. Long on September 17, 2012;

r) Patient T.D., age 68, who was treated by Dr. Petty on September 17, 2012;

s) Patient J.G., age 80, who was treated by Dr. Petty on September 17, 2012;

t) Patient G.H., age 74, who was treated by Dr. Petty on September 17, 2012;

u) Patient L.K., age 67, who was treated by Dr. Lenns on September 17, 2012;

v) Patient B.J., age 85, who was treated by Dr. Long on September 17, 2012;

w) Patient J.L., age 83, who was treated by Dr. Petty on September 17, 2012;

x) Patient W.C., age 69, who was treated by Dr. Petty on September 18, 2012;

y) Patient Y.C., age 75, who was treated by Dr. Long on September 19, 2012;

z) Patient M.H., age 90, who was treated by Dr. Petty on September 19, 2012;

aa) Patient J.K., age 75, who was treated by Dr. Petty on September 19, 2012;

bb) Patient P.H., age 69, who was treated by Dr. Long on September 19, 2012;

cc) Patient S.P., age 65, who was treated by Dr. Petty on September 19, 2012;

dd) Patient R.C., age 80, who was treated by Dr. Petty on September 20, 2012;

ee) Patient J.I., age 81, who was treated by Dr. Long on September 20, 2012;

ff) Patient N.K., age 68, who was treated by Dr. Petty on September 20, 2012;

gg) Patient C.L., age 71, who was treated by Dr. Lenns on September 20, 2012;

hh) Patient H.P., age 72, who was treated by Dr. Long on September 20, 2012;

ii) Patient A.H., age 81, who was treated by Dr. Long on September 21, 2012;

jj) Patient E.K., age 76, who was treated by Dr. Lenns on September 24, 2012;

kk) Patient L.K., age 71, who was treated by Dr. Lenns on September 24, 2012;

ll) Patient M.P., age 77, who was treated by Dr. Petty on September 24, 2012;

mm) Patient S.K., age 70, who was treated by Dr. Petty on September 25, 2012;

nn) Patient G.D., age 71, who was treated by Dr. Long on September 25, 2012;

oo) Patient D.M., age 77, who was treated by Dr. Petty on September 25, 2012;

pp) Patient P.C., age 76, who was treated by Dr. Long on September 26, 2012;

qq) Patient P.H., age 69, who was treated by Dr. Petty on September 26, 2012;

rr) Patient G.J., age 72, who was treated by Dr. Long on September 26, 2012;

ss) Patient H.C., age 83, who was treated by Dr. Long on September 27, 2012;

tt) Patient J.H., age 73, who was treated by Dr. Petty on September 27, 2012;

uu) Patient M.L., age 92, who was treated by Dr. Petty on September 27, 2012;

vv) Patient E.D., age 69, who was treated by Dr. Petty on September 28, 2012;

ww) Patient T.K., age 65, who was treated by Dr. Long on September 28, 2012;

xx) Patient G.W., age 70, who was treated by Dr. Petty on December 13, 2012;

yy) Patient C.M., age 69, who was treated by Dr. Long on December 13, 2012;

zz) Patient D.A., age 75, who was treated by Dr. Long on December 13, 2012;

aaa) Patient J.W., age 77, who was treated by Dr. Binamira on December 13, 2012;

bbb) Patient G.M., age 66, who was treated by Dr. Long on December 17, 2012;

ccc) Patient J.W., age 74, who was treated by Dr. Petty on December 17, 2012;

ddd) Patient J.F., age 67, who was treated by Dr. Petty on December 17, 2012;

eee) Patient H.H., age 84, who was treated by Dr. Lenns on December 17, 2012;

fff) Patient C.G., age 77, who was treated by Dr. Binamira on December 18, 2012;

ggg) Patient M.H., age 72, who was treated by Dr. Petty on December 19, 2012;

hhh) Patient I.B., age 87, who was treated by Dr. Binamira on December 19, 2012;

iii) Patient N.W., age 66, who was treated by Dr. Petty on December 20, 2012;

jjj) Patient J.R., age 68, who was treated by Dr. Binamira on December 20, 2012;

kkk) Patient S.S., age 72, who was treated by Dr. Long on December 21, 2012;

lll) Patient W.B., age 72, who was treated by Dr. Long on December 21, 2012;

mmm) Patient F.W., age 77, who was treated by Dr. Long on December 21, 2012;

nnn) Patient R.E., age 68, who was treated by Dr. Petty on January 8, 2013;

ooo) Patient L.M., age 65, who was treated by Dr. Lenns on January 10, 2013;

ppp) Patient S.M., age 66, who was treated by Dr. Long on January 10, 2013;

qqq) Patient V.D., age 69, who was treated by Dr. Petty on January 10, 2013;

rrr) Patient R.B., age 71, who was treated by Dr. Petty on January 10, 2013;

sss) Patient E.F., age 85, who was treated by Dr. Lenns on January 17, 2013;

ttt) Patient E.K., age 76, who was treated by Dr. Long on January 17, 2013;

uuu) Patient M.N., age 69, who was treated by Dr. Lenns on January 17, 2013;

vvv) Patient N.T., age 81, who was treated by Dr. Petty on January 17, 2013;

www) Patient P.G., age 77, who was treated by Dr. Petty on January 28, 2013;

xxx) Patient D.H., age 74, who was treated by Dr. Binamira on January 28, 2013;

yyy) Patient P.M., age 78, who was treated by Dr. Petty on February 8, 2013;

zzz) Patient E.C., age 68, who was treated by Dr. Lenns on February 8, 2013;

aaaa) Patient E.J., age 66, who was treated by Dr. Petty on February 8, 2013;

bbbb) Patient R.C., age 79, who was treated by Dr. Petty on February 11, 2013;

cccc) Patient D.H., age 76, who was treated by Dr. Petty on February 11, 2013;

dddd) Patient M.D., age 71, who was treated by Dr. Petty on February 11, 2013;

eeee) Patient G.R., age 76, who was treated by Dr. Long on February 19, 2013;

ffff) Patient G.R., age 70, who was treated by Dr. Petty on February 22, 2013;

gggg) Patient J.M., age 65, who was treated by Dr. Petty on February 22, 2013;

hhhh) Patient J.S., age 78, who was treated by Dr. Long on February 22, 2013;

iiii) Patient L.C., age 81, who was treated by Dr. Petty on February 22, 2013;

jjjj) Patient A.S., age 90, who was treated by Dr. Petty on February 22, 2013;

kkkk) Patient D.E., age 76, who was treated by Dr. Petty on March 4, 2013;

llll) Patient H.B., age 69, who was treated by Dr. Long on March 4, 2013;

mmmm) Patient C.M., age 80, who was treated by Dr. Lenns on March 4, 2013;

nnnn) Patient M.C., age 90, who was treated by Dr. Binamira on March 15, 2013;

oooo) Patient L.G., age 90, who was treated by Dr. Binamira on March 15, 2013;

pppp) Patient G.J., age 73, who was treated by Dr. Long on March 27, 2013;

qqqq) Patient J.B., age 69, who was treated by Dr. Petty on April 1, 2013;

rrrr) Patient D.B., age 73, who was treated by Dr. Lenns on April 1, 2013;

ssss) Patient H.B., age 69, who was treated by Dr. Lenns on April 1, 2013;

tttt) Patient G.L., age 70, who was treated by Dr. Long on April 2, 2013;

uuuu) Patient S.L., age 73, who was treated by Dr. Petty on April 2, 2013;

vvvv) Patient M.D., age 74, who was treated by Dr. Petty on April 2, 2013;

wwww) Patient B.S., age 84, who was treated by Dr. Lenns on April 2, 2013.

Defendants Violated the Anti-Kickback and Stark Statutes

84. Through their offers of remuneration for blood samples drawn and sent to Defendant laboratories, Defendants incentivized physicians to increase patient referrals to their labs, or in the case of BlueWave, the labs with which it contracts. As discussed above, a 2005 OIG Advisory Opinion dealt with a substantially similar reimbursement program, although in the proposed program only $3 to $6 would be reimbursed to the physicians per blood draw. The Opinion found that where a laboratory pays a physician an amount higher than the laboratory receives in Medicare reimbursement to perform blood draws, one can infer that the payments were meant to induce referrals. It also went on to find that such a program creates a risk of overutilization and inappropriate higher costs to federal health care programs.

85. The current case is even more problematic than the situation reviewed by HHS OIG in the Advisory Opinion because, here, Defendants paid the physicians three times fair market value or more.

86. As in the Advisory Opinion, this arrangement does not qualify for the professional services safe harbor because the arrangement was not set out in writing, and the fees to be paid to the physicians were not set in advance.

87. The inflated rates at which Defendants "reimbursed" physicians evidence their intent to use the payments, not as true reimbursement, but as incentive to increase the number of tests physicians order from the labs. Even if reimbursement is one purpose of the payments, Defendants are still in violation of the AKS because, upon information and belief, increasing referrals was also a purpose.

88. Defendants are also in violation of the Stark Statute. The payments that physicians receive are compensation, creating a "financial relationship" within the meaning of

the statute. Thus, each claim submitted to Federal Health Care program for a test performed for a physician whom Defendants pay drawing fees is a violation of the Stark Statute.

89. Each claim submitted in violation of Stark or the AKS is a false claim within the meaning of the False Claims Act. Thus, through their illegal conduct, Defendants have submitted or caused to be submitted thousands of false or fraudulent claims to Medicare, Medicare Advantage providers and other government health care programs. Additionally, defendant BlueWave entered into one or more conspiracies with test provider defendants HDLab and Singulex to submit or cause to be submitted false or fraudulent claims to government health care programs. Furthermore, because of the same Stark and AKS violations, Defendants caused any and all claims for reimbursement of blood drawing fees that were submitted to federal health care programs with respect to patients for whom Defendants paid the presenting providers such separate "drawing fees" or "process and handling fees" to be false claims within the meaning of the FCA.

B. Quest Diagnostics and Berkeley HeartLab Offered Providers Additional Remuneration to Induce Patient Referrals After Berkeley's Draw Fee Payments to Physicians Were Terminated

90. As explained above, Quest terminated Berkeley's drawing fee program January 31, 2012, ending the $11.50 per patient referral payments to providers. On January 10, 2010, Quest representative, Marc Biemiller, met with Relator and his partner physicians and explained to the practice that the legal department at Quest insisted that the drawing fee policy change because the Government was "starting to crack down." Biemiller reported that the "drawing fee payments" were to cease after January 31, 2012 for all providers, with the exception of hospitals which Berkeley continues to pay $25 per patient referral. Upon information and belief, despite acknowledging the illegality of the excessive blood drawing fees, Quest made no plans to disclose to CMS the countless unlawful payments that Berkeley and Quest had previously made and never volunteered such information to CMS.

91. Although the termination of the drawing fee kickbacks should have marked a step in the right direction, Quest and Berkeley developed a plan to replace the drawing fees with several new forms of illegal remuneration. As Biemiller told the HMP physicians, Quest recognizes that the "drawing fees" incentivized provider referrals to Berkeley and that the termination of those payments would adversely affect the number of Berkeley tests that physicians ordered. Thus, Quest developed ways to try to "get around" the drawing fee restrictions (i.e., continue providing kickbacks to physicians). Biemiller explained openly and directly that Quest offers these new forms of remuneration for the purpose of providing alternate compensation to those physicians who would be losing the Berkeley drawing fee revenue. On the basis of these facts, and on information and belief, Quest and Berkeley have offered and provided these kickbacks to providers nationwide.

92. Principally, Quest offered to begin paying the full salary of Heritage Medical Partners' phlebotomist, Robin Spikes. Under the terms of the offer made to and ultimately accepted by HMP, Quest has taken over payment of the entirety of their phlebotomist's salary and expenses. As of July 13, 2012, Ms. Spikes is officially employed by Quest. Under the new arrangement, Ms. Spikes technically works out of Quest's building, however, the building is located directly across the parking lot from HMP's offices, and Quest actually leases the space from HMP. Furthermore, in exchange for the physicians' promise to continue referring patients to Berkeley for testing, Quest has promised HMP that Ms. Spikes will perform the blood draws for all the lab tests HMP orders, even the basic test panels that HMP performs in their offices.

93. Under such an arrangement the only change for the medical practice is the source of financing for the phlebotomist. Thus, the salary payments essentially function as monetary gifts from Quest, kickbacks to the practice.

94. Under certain circumstances, providers may be given the use of a laboratory paid phlebotomist without implicating the Anti-Kickback Statute, however, such a provider-

laboratory arrangement must abide by certain guidelines. As explained in an OIG Special Fraud Alert, "[w]hile the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's staff" because "a strong inference arises that he or she is providing a benefit in return for the physician's referral to the laboratory." Dep't of Health and Human Services, Office of Inspector Gen., Special Fraud Alert, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994). OIG has since cited this Special Fraud Alert analysis as an extension of the broader principle that "[i]f the intent of providing free goods or services is to induce or reward referrals of Federal health care program business, the anti-kickback statute would be violated." Dep't of Health and Human Services, Office of Inspector Gen., Advisory Opinion No. 98-16 (Nov. 3, 1998), *available at* http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_16.htm.

95. Quest's offer to begin paying the salary of a practice's phlebotomist is not consistent with the permissible laboratory-provider arrangement explained by the OIG. The fact that Quest would be taking over the salary payments of the physician group's existing employee, rather than merely offering the services of a Quest employee raises red flags. More significant, however, is the fact that Quest explicitly offered this benefit to physicians in order to induce continued referrals. This alone renders Quest's salary payment offer a direct violation of the Anti-Kickback Statute.

96. Quest also offered to make up lost draw fee revenue in other ways, including leasing more than 200 square feet of office space from HMP. Quest told the physicians that it would use this space for Berkeley's 4myheart program. No specific rental price was offered, however, even if Quest were to lease the space at a price reflecting fair market value, this arrangement would still violate the Anti-Kickback Statute as the lease and consequent rental payments were offered for the purpose of providing revenue to physicians who would be expected to reciprocate with lab referrals to Berkeley.

97. Additionally, Quest has offered to seamlessly integrate HMP's electronic medical records system with Quest's system, allowing the physicians immediate access to their patient's lab results. Biemiller explained that this would be a "valuable benefit" to HMP, offered by Quest at no cost. The Anti-Kickback Statute contains a safe harbor protecting the provision of "software or information technology…used predominantly to create, maintain, transmit, or receive electronic health records." 42 C.F.R. § 1001.952(y). However, the safe harbor protection does not apply if the "eligibility of the recipient…is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties." Id. at § 1001.952(y)(5). Additionally, the software integration that Quest has offered would likely not meet the safe harbor's requirement that the technology "contain[] electronic prescribing capability." Id. at § 1001.952(y)(10).

98. Quest has further offered to make up for the loss of the drawing fee remuneration paid for referrals of government-insured patients by paying the physicians hugely inflated drawing fees for their commercial insurance patients. Certain private insurers are willing to pay exorbitant fees for certain blood draw collections and Quest has offered to pass those high drawing fee payments on to the physicians. For example, according to Biemiller, Blue Cross Blue Shield reimburses $560 for each Plavix Test, of which almost $200 are designated the drawing fee. Even more egregiously, when Relator asked how they could be paid drawing fees if Quest were paying the salary of HMP's phlebotomist, Biemiller assured him that it would not be a problem, and Quest would "pass through" the nearly $200 fee each time an HMP physician ordered a Plavix Test for a commercial insurance patient.

99. Quest's payment of phlebotomists' salaries, leasing of office space, integration of electronic medical records systems and payment of exorbitantly high drawing fees for commercial patients all constitute illegal inducements in violation of the Anti-Kickback Statute. Quest agreed with Berkeley to provide these kickbacks, and submit or cause the

submission of the resulting claims to government health care programs in violation of the FCA.

C. Berkeley, BlueWave, HDLab and Singulex Submitted or Caused the Submission of Claims for Medically Unnecessary Procedures

100. Medicare payment is limited to those services, including clinical laboratory services, which are reasonable and necessary for the diagnosis or treatment of illness or injury. 42 U.S.C. § 1395y(a)(1)(A). Additionally, clinical laboratory services must be ordered and used by the physician who is treating the beneficiary or by a qualified nonphysician practitioner. Laboratory tests that are not ordered by the treating physician or practitioner are not eligible for Medicare coverage. 42 C.F.R. § 410.32(a). Even where an interpreting physician determines a different diagnostic test is appropriate, he or she cannot do so until a new order from the treating physician or practitioner has been received. See Medicare Benefit Policy Manual, Chapter 15 § 80.6.2 (Rev. 131, August 20, 2010).

1. Berkeley

101. When the HMP physicians first spoke with Berkeley's representative, he encouraged them to order tests in bundled "panels," rather than individually. Thus, the rep explained that physicians could order one set of tests, the "Baseline Panel," for patients presenting with hyperlipidemia and a second set, the "Follow Up Panel," to follow up with patients who had previously been diagnosed with hyperlipidemia and were receiving treatment. Both Berkeley Panels, as explained to the HMP physicians, would include Apo B, HDL-S_{10}GGE, LDL-S_3GGE, Lipoprotein (a) and Lp-PLA_2. In addition, the Baseline Panel would include the Apo E, KIF6 and LPA Genotype tests in patients who had previously not had the genetic testing.

102. Berkeley's representative pushed the physicians to order the panels, rather than individual tests, even going so far as to provide the physician with "berkeley baseline" and "berkeley follow up" stamps. The official Berkeley order form provides check boxes which physicians could use to order the panels or individual tests. However, Berkeley encouraged

the physicians to use the stamps to order the panels for patients on internal order forms, which HMP's billing could then translate to the official Berkeley order form. Thus, Berkeley knew that the physicians themselves never had reason to fill out or even look at the Berkeley order forms.

103. Berkeley provided HMP's billing staff with sets of Berkeley order forms. The majority of the order form is standardized for all practices, however, Berkeley specially printed a section where HMP's billing personnel could select the Baseline or Follow Up panel. Berkeley also pre-printed the practice name and address as well as check boxes to mark the individual referring physician within HMP.

104. In approximately December of 2010, Berkeley informed the physicians that they offer the CYP2C9 Genotype Test designed to show whether a patient would respond to Plavix. As explained above, Plavix is commonly used to treat patients at risk for blood clots, such as those who have had a stroke, transient ischemic attack (stroke-like symptoms often considered a warning sign that a true stroke may occur in the future) or myocardial infarction (heart attack), or patients who have received a stent placement. However, certain patients, those without normal CYP2C19 metabolite function, are unable to effectively metabolize Plavix. In these patients, Plavix has actually been shown to increase rates of cardiovascular events. The Plavix test identifies a patient's CYP2C19 genotype, predicting the patient's ability to metabolize Plavix. Thus, the Plavix test is not necessary unless the referring physician is considering treating the patient with Plavix.

105. When the Berkeley sales representative first presented the Plavix test, he told the HMP physicians that Berkeley would pay an additional $7.50 draw fee when they ordered a Plavix test in addition to the traditional Berkeley panel. The Berkeley representative suggested that this could be done in one of two ways, either the $7.50 could be added to the traditional $11.50 draw fee, or the Plavix test could be ordered on a separate day from the full panel in order to justify a second draw fee. The HMP physicians responded that they would have to discuss this additional draw fee before making any decisions.

106. The HMP physicians discussed ordering the Plavix test for individual patients as needed, but never discussed adding it to one of the Berkeley panels. Nevertheless, approximately one month after the conversation with Berkeley's sales representative, Berkeley began adding the Plavix test to every follow-up lab ordered for a patient with hyperlipidemia (high blood cholesterol and triglycerides). Follow-up labs are routinely ordered for patients with high cholesterol, the vast majority of whom are not under consideration for treatment with Plavix. Berkeley added the Plavix test to the "Follow Up Panel" on the official order forms sent to HMP's billing staff. However, as Berkeley knew, those order forms were not completed by HMP's physicians, and a physician had no other way of knowing that the Plavix test would be performed on a patient until he or she received the lab report with the results.

107. For example, in or about October 2010, Dr. Mayes treated a seventy-six year old female, Patient A, for whom he ordered a Berkeley CVD test profile. Most of the tests came back normal, but her Apo B (total LDL count) was in the intermediate range indicating some risk for heart disease, and her NT-proBNP hormone test indicated that her heart was being overworked on a continual basis, suggesting structural or cardiac dysfunction. Approximately two months later, Dr. Mayes had a follow up visit with Patient A and submitted an order for follow-up testing from Berkeley. Patient A was not taking Plavix, she did not need a Plavix test, and Dr. Mayes did not request a Plavix test. Berkeley nevertheless performed a Plavix test on Patient A's blood sample.

108. In addition to the unnecessary Plavix tests, Relator observed that Berkeley routinely runs NT-proBNP and Vitamin D tests on nearly every patient for whom a Berkeley Baseline or Follow Up Panel was ordered, even though neither test was originally included in the agreed-upon panels. After requesting from HMP's billing the official order forms of patients who had received unordered Vitamin D and NT-proBNP tests, Relator learned that

Berkeley had begun adding these tests to both panels on the pre-printed forms sent to the billing staff.

109. Vitamin D levels are traditionally tested in patients with osteoporosis, osteopenia, or other evidence of vitamin D deficiency. However, the only patient diagnostic information that HMP provides Berkeley is any previous diagnosis of hyperlipidemia. Berkeley is not given any diagnostic information from which they could conclude a patient may be at risk for vitamin D deficiency. Nevertheless, Berkeley has added Vitamin D tests to their routine panels and performed them when they were not knowingly ordered by the referring physician, and were not medically necessary.

110. Similarly, the NT-proBNP lab is only necessary in patients who have dyspnea (shortness of breath), congestive heart failure or cardiomyopathy. It should not be performed as part of a routine lipid analysis and was never agreed upon as a test that should be included in one of the Berkeley panels. However, even where physicians ordered only a Baseline or Follow Up Panel and provided Berkeley with no diagnosis other than hyperlipidemia, Berkeley has routinely added the medically unnecessary NT-proBNP test.

111. For example, Dr. Mayes submitted follow-up testing for Patient A, discussed above, and did not request a Vitamin D test. The patient did not present with signs of vitamin D deficiency, and he provided Berkeley no information from which they could have concluded that the patient may be vitamin D deficient. Despite the lack of physician order, Berkeley performed the medically unnecessary test.

112. Additionally, in approximately January of 2011, Relator referred patients G.F. and M.A.F., both Medicare patients, to Berkeley for testing. Neither patient was on Plavix or needed Plavix, and Relator did not order a Plavix test for either patient. Nevertheless, Berkeley performed Plavix tests on both patients and submitted claims for the medically unnecessary tests to Medicare. Similarly, Berkeley performed Vitamin D tests on both patient G.F. and patient M.A.F., and billed Medicare for the tests, although Relator did not order a Vitamin D test for either patient, nor did HMP provide Berkeley with any information from

which they could have concluded that either patient was vitamin D deficient. Berkeley also performed unordered, unnecessary NT-proBNP tests on patient G.F. in March and August of 2010, and performed unordered, unnecessary NT-proBNP tests on both patient G.F. and patient M.A.F. with their traditional Berkeley test profiles in January of 2011. Medicare reimbursed Berkeley $341.42 for each patient's Plavix test, $41.66 for each Vitamin D test, and between $47.77 and $48.62 for each NT-proBNP test.

113. Likewise, in April of 2011, Relator referred patient M.T.F. to Berkeley for testing, but did not order Plavix, Vitamin D or NT-proBNP testing, nor did the patient need any of the three tests. Even so, Berkeley performed Plavix, Vitamin D and NT-proBNP tests on patient M.T.F., billed Medicare and was reimbursed a total of $430.85 for the three tests.

114. Berkeley regularly performed Plavix tests on any patient, previously found to have hyperlipidemia, whose blood sample was sent for follow-up tests, regularly performed Vitamin D tests on patients who presented with no evidence of vitamin D deficiency, and regularly performed NT-proBNP tests on patients presenting with no diagnosis other than hyperlipidemia. Thus, Berkeley performed numerous medically unnecessary tests that were never knowingly ordered by the referring physician. Upon information and belief, a high percentage of these patients were under coverage by Medicare, and claims for these unnecessary tests were submitted to Medicare and other federal health care programs. Because such unnecessary, unprescribed testing was done at Berkeley's centralized lab, Relator believes and therefore alleges that such practices occurred with respect to prescriptions for testing that came to Berkeley from anywhere nationwide. Each claim submitted to a federal health care program for a test that was medically unnecessary or not ordered by a physician constitutes a false claim within the meaning of the False Claims Act.

2. BlueWave, HDLab and Singulex

115. BlueWave, HDLab and Singulex also promote the universal use of lab panels that include tests that are not medically necessary, or even helpful, for every patient.

116. The baseline panel offered by BlueWave includes the CYP2C19 Plavix test which HDLab runs for every patient unless the referring physician specifically requests that it not be included in the panel, even though it is only useful for patients taking Plavix or for whom the physician is considering Plavix.

117. BlueWave also includes a Factor V Leiden ("FVL") genetic mutation test and a prothrombin G20210A mutation test in the baseline panel, both of which are performed by HDLab for every patient unless specifically deselected by the referring physician, despite limited necessity. HDLab actually admits that the FVL test is only recommended for "a patient who has a personal or family history of recurrent [venous thromboembolism ("VTE")], has a first VTE while taking oral contraceptives/[hormone replacement therapy], or during pregnancy." See Dawn L. Thiselton, Testing for Factor V Leident and prothrombin G20210A mutations, HDL Clinical Articles, http://www.hdlabinc.com/sciencebulletin/clinical-articles/testing-for-factor-v-leiden-and-prothrombin-g20210a-mutations. However, despite acknowledging that expert guidelines[4] do not recommend FVL and prothrombin mutation genetic screening for all patients, HDLab nevertheless claims that, given the newly lowered costs of these tests, their "utility…extends to everybody." Id.

118. In addition, the panel marketed by BlueWave includes the following HDLab tests in their baseline *and* follow-up panels:

a) Tests measuring homocysteine levels, which are generally only run for patients with unexplained blood clots or unexplained atherosclerosis, or in those with suspected Vitamin B-12 or folic acid deficiencies;

[4] In fact, recently released expert guidance specifically recommends *against* routine testing for FVL and/or prothrombin 20210A in adults with idiopathic VTE and asymptomatic adult family members of patients with VTE and an FVL or prothrombin mutation, warning that "potential benefits are unlikely to exceed potential harms." A.O. Berg et al., Recommendations from the EGAPP Working Group: routine testing for Factor V Leiden (R506Q) and prothrombin (20210G>A) mutations in adults with a history of idiopathic venous thromboembolism and their adult family members, GENET. MED., Jan. 2011, at 67-76.

b) Vitamin D tests for all patients, including those that have shown no signs of Vitamin D deficiency; and

c) Tests measuring HbA1c levels, which show average blood glucose concentrations, information which is typically useful only for patients that are hyperglycemic or diabetic.

119. In addition to the above-named tests, BlueWave's baseline and follow-up panels include several HDLab tests that most providers would not order for every patient, including tests for Myeloperoxidase levels, Galectin-3 levels, Apolipoprotein A1 levels, free fatty acid levels, omega-3 fatty acid levels and methylenetetrahydrofolate reductase ("MTHFR") genetic mutation (baseline panel only).

120. BlueWave also includes several Singulex tests in their baseline and follow-up panels that most providers would only order for small, select groups of patients. For example, BlueWave runs cTnI tests on every patient's baseline and follow-up panel unless the test is actively removed by the referring physician, even though cTnI labs are typically ordered only for patients with suspected active cardiac injury.

121. The panels also include IL-6 and IL-17A tests. Although elevated levels of IL-6 or IL-17A may be indicative of cardiovascular problems, such as coronary artery disease and myocardial infarction, they are also associated with a myriad of other conditions. Thus, IL-6 and IL-17A test results are of very low clinical utility for screening or diagnosis, and should not be performed as part of a routine panel of screening tests.

122. Additionally, the BlueWave panels include the Singulex-designed "Advanced Panel" which consists of several labs including tests measuring PTH and ferritin, neither of which should be performed routinely on a baseline panel. PTH tests are generally ordered only for patients with abnormal levels of vitamin D, calcium or phosphorus. Ferritin tests are typically ordered only for patients suspected of having high or low iron levels. Singulex attempts to promote the utility of the Ferritin test in a widespread population, claiming, in a

handout given to physicians, that elevated ferritin levels "may reflect subclinical inflammation" and "may also be a predictor of future development of diabetes." However, even Singulex admits that elevated ferritin levels may result from a wide variety of causes, including liver disease, chronic infection, autoimmune disorders, alcohol abuse, and hepatitis and thus the Ferritin test results have relatively limited diagnostic utility when performed on a screening basis.

123. As the coordinator between providers and HDLab and Singulex, BlueWave is responsible for the tests included in their baseline and follow-up panels. However, the actual order forms listing the tests included in each panel were printed on forms produced by HDLab and Singulex, and the defendant laboratories received the orders and performed and billed for the tests. Upon this basis, and the fact that HDLab and Singulex knowingly engaged BlueWave to market their tests jointly on their behalves, Relator believes and therefore alleges that BlueWave entered into one or more conspiracies with HDLab and Singulex to bundle and market medically unnecessary tests.

124. In addition to the tests included in the baseline and follow-up panels, in the summer of 2012, BlueWave began pushing a new test panel offered by HDLab, Early CDT®-Lung, which tests for early signs of lung cancer by measuring the amount of six different antigens. BlueWave encouraged Relator and his partners to order the test for anyone who smokes or formerly smoked. Furthermore BlueWave provided the HMP physicians with the series of diagnosis codes that would trigger Medicare reimbursement as often as once per year, even where a patient's initial test is negative for indications that the patient is at risk of developing lung cancer.

125. By pushing tests for a generalized category of patients such as current and former smokers and by bundling tests together, rather than permitting providers to choose the individual tests needed for each patient, BlueWave, HDLab and Singulex have caused providers to order countless unnecessary labs. Thus, BlueWave, HDLab and Singulex have

caused claims for medically unnecessary tests to be submitted to insurers, including Medicare and other federal health care programs. Each claim for a medically unnecessary test submitted to a federal health care program is a false claim within the meaning of the False Claims Act.

Count I
False Claims Act
31 U.S.C. §§ 3729(a)(1)(A)

126. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 125 above as though fully set forth herein.

127. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

128. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

129. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by several separate entities, across the United States. Relator has no control over or dealings with such entities and has no access to the records in their possession.

130. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

131. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

132. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

Count II
False Claims Act Conspiracy
31 U.S.C. § 3729(a)(1)(c)

133. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 132 above as though fully set forth herein.

134. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

135. By virtue of the acts described above, defendant BlueWave Healthcare Consultants knowingly entered into one or more conspiracies with defendants HDLab and Singulex to present or cause to be presented, false or fraudulent claims to the United States Government for payment or approval.

136. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by Defendants HDLab and Singulex. Relator has no control over or dealings with these entities and has no access to the records in their possession.

137. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by BlueWave's conspiracies with HDLab and Singulex, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

138. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

139. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

VII. PRAYER

WHEREFORE, *qui tam* Relator Dr. Mayes prays for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 et seq.;

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions,

plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

3. That Dr. Mayes be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

4. That Dr. Mayes be awarded all costs of this action, including attorneys' fees and expenses; and

5. That Dr. Mayes recover such other relief as the Court deems just and proper.

VIII. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, *qui tam* Relator Dr. Mayes hereby demands a trial by jury.

Respectfully submitted,

/s/ William A. Coates

William A. Coates, Fed. ID No. 183
Roe Cassidy Coates & Price, P.A.
1052 North Church Street
Greenville, South Carolina 29601
Tel: (864) 349-2600
Fax: (864) 349-0303

OF COUNSEL:
Peter W. Chatfield
Phillips & Cohen, LLP
2000 Massachusetts Ave. NW
Washington, D.C. 20036
Tel: (202) 833-4567
Fax: (202) 833-1815

Greenville, South Carolina

August 5, 2014